Reference number(s)
3469-A

SPECIALTY GUIDELINE MANAGEMENT

PADCEV (enfortumab vedotin-ejfv)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Padcev (enfortumab vedotin-ejfv) is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Urothelial Cancer
Authorization of 12 months may be granted for treatment of locally advanced or metastatic urothelial cancer (e.g., bladder cancer and cancers of the urinary tract) as a single agent when both of the following criteria are met:
1. Member has received prior treatment with a platinum-containing chemotherapy.
2. Member has received prior treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Padcev [package insert]. Northbrook, IL: Astellas Pharma; December 2019.